

EXHIBIT 14



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EXAMINER
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The time period for reply, if any, is set in the attached communication.



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In re Application of:
Ho et al. :
Serial No.: 09/960,244 : PETITION DECISION
Filed: September 21, 2001 :
Attorney Docket No.:
2560.0020000/JAG/D-S :

This is in response to the petition under 37 CFR § 1.181(a)(1), filed June 16, 2009, requesting that the examiner's requirement to cancel allegedly new matter set forth in the Office action of March 16, 2009 be reviewed and rescinded.

BACKGROUND

The petition concerns the issue of whether or not the amendment of March 5, 2008 resulted in the addition of new matter to the specification.

On March 5, 2008, Applicants submitted an amendment containing, *inter alia*, amendments to the specification removing a sentence from the end of Example 1 and adding it to the middle of Example 3.

On March 27, 2008, an interview was conducted between the examiner's supervisor and two of Applicants' representatives. On April 3, 2008, a second interview was conducted between the examiner, the examiner's supervisor, and the same two representatives. The record does not indicate that the amendments to the specification submitted March 5, 2008 were discussed.

On July 7, 2008, Applicants submitted a supplemental amendment comprising amendments to the claims and remarks, but no further amendments to the specification.

On March 16, 2009, the examiner mailed to Applicants a non-final Office action containing, *inter alia*, an objection to the amendment filed July 7, 2008 for introducing new matter into the specification. Since the examiner specifically referred to the sentence moved from Example 1 to Example 3, it is assumed that the reference to the amendment of July 7, 2008 was an inadvertent error and that the examiner intended to refer to the amendment of March 5, 2008. Such is also assumed by Applicants, as evidenced by footnote 2 appearing at p. 2 of the petition.

On June 16, 2009, Applicants submitted the instant petition.

DISCUSSION

The petition and the file history have been carefully considered.

In the petition, Applicants argue that the amendments to the specification were made to correct minor clerical errors, and that the amendments were not material to patentability. Applicants argue that the amendment at issue is supported by the original disclosure, does not change the description of the invention, and does not introduce new matter, especially considering the sentence being moved from Example 1 to Example 3 was the exact same sentence. Applicants urge that moving the sentence to Example 3 was in order to place this sentence, which refers to cells of Figure 1B, immediately after a sentence referring to Master Cell Bank in order to provide additional clarity that the cells shown in Figure 1B may be referred to by the arbitrary designation of Master Cell Bank cells. Applicants further argue that the claims do not refer to, nor require, any reference to a Master Cell Bank. Applicants argue that Examples 1 and 3 are not distinct, but that Example 3 continues the procedure outlined in Example 1. Finally, Applicants argue that the examiner did not object to an almost identical request to move a sentence from Example 2 to Example 3.

Example 1 of the specification as originally filed describes a procedure of isolating cells from bone marrow aspirates following red blood cell lysis. The end of Example 1 in the specification as originally filed describes the adherent population of cells obtained from the method with these sentences:

CD45, CD49c and CD90 in the cultured bone marrow cells was assessed. The adherent population derived from mononuclear cells initially purified using ammonium chloride lysis contained approximately 70% CD49c positive cells at a similar stage of culture (Figure 1A). The majority of cells that did not express CD49c were positive for expression of hematopoietic/myeloid lineage marker CD45 (Figure 1A, LR quadrant), demonstrating that the CD49c positive cell population derived from human bone marrow isolated was not directly related to known hematopoietic precursors. More than 94% of the adherent population was CD90 and CD49c positive (Figure 1B).

Therefore, the specification as originally filed indicated that the procedure set forth in Example 1 resulted in a cell population in which over 94% of the adherent cells were CD90 and CD94c positive. Example 3 is a continuation of the procedure of Example 1, and describes additional steps taken on the cells obtained in Example 1. These include culturing 7-10 days, removal of cells from flasks, washing, cooling/storing, replating and culturing for two weeks, removal of cells from plates, and cryopreservation. Page 28, lines 19-21 indicate that these cells were the "Master Cell Bank." The amendment to Example 3 indicates that more than 94% of the cells in the Master Cell Bank were CD90 and CD94c positive. Therefore, the amendment moving the

sentence at issue from Example 1 to Example 3 introduces new matter into the specification, since the amended specification discloses that additional steps set forth in Example 3 must be carried out on the cells obtained by the procedure of Example 1 in order to obtain a cell population wherein more than 94% of the cells in the Master Cell Bank were CD90 and CD94c positive.

There is no evidence of record that the sentence at issue should have appeared in Example 3 originally, and that its appearance in Example 1 in the specification as originally filed was a clerical error. It is noted that *Ex parte Marsili*, 214 USPQ 904 (BPAI 1979), and *Ex parte Maizel*, 27 USPQ2d 1662 (BPAI 1992), both indicate the desirability of correcting errors. However, in both cases, evidence was submitted showing that the inventors were in possession of the compounds at issue at the time of filing, as well as when the errors in the chemical structures were identified, and what steps were taken to correct the errors. No such evidence has been submitted in the instant application.

Regarding the move of a phrase from Example 2 to Example 3, the fact pattern is clearly distinguished from that of the move of a sentence from Example 1 to Example 3. Specifically, the amendment to Example 3 is as follows:

Similarly, the master cell bank generated from the CFU derived using the method of Example 2 showed that more than 91% of the adherent population was CD90 and CD49c positive (Figure 2B) and the majority of cells (>98.8%) of the resulting cell population expressed CD90 CD49c (Figure 2C) and virtually lacked any expression of the myeloid-related marker CD45 (Figure 2C, LR quadrant). Thus, the expansion procedure as described herein generates a substantially homogenous population of adherent cells which co-express CD49c and CD90 and lack significant expression of the marker CD45.

Thus, the phrase appears in Example 3 only at a place that references the cells of Example 2. Such does not constitute new matter.

DECISION

The petition is subsequently **DENIED**.

A notice of appeal has been filed 16 June 2009. To avoid abandonment, Applicants must file a response in accordance with the time period set forth in 37 C.F.R. § 41.37(a).

Should there be any questions about this decision please contact Quality Assurance Specialist Marianne C. Seidel, by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 703-872-9306.



Remy Yucel
Director, Technology Center 1600